



Government
of Canada

Gouvernement
du Canada

[Canada.ca](#) > [Departments and agencies](#) > [Health Canada](#)

Health Canada authorizes first COVID-19 vaccine

From: [Health Canada](#)

Statement

December 9, 2020

Ottawa, ON

Health Canada

Thanks to advances in science and technology, and an unprecedented level of global cooperation, today, Canada reached a critical milestone in its fight against COVID-19 with the authorization of the first COVID-19 vaccine.

Health Canada received Pfizer's submission on October 9, 2020 and after a thorough, independent review of the evidence, Health Canada has determined that the Pfizer-BioNTech vaccine meets the Department's stringent safety, efficacy and quality requirements for use in Canada.

As part of its continued commitment to openness and transparency, Health Canada is publishing [a number of documents](#) related to this decision, including a high-level summary of the evidence that Health Canada reviewed to support the authorization of the vaccine. More detailed information will be available in the coming weeks, including a detailed scientific summary and the full clinical trial data package.

Canadians can feel confident that the review process was rigorous and that we have strong monitoring systems in place. Health Canada and the Public Health Agency of Canada will closely monitor the safety of the vaccine once

it is on the market and will not hesitate to take action if any safety concerns are identified.

The terms and conditions of the Pfizer-BioNTech vaccine authorization require the manufacturer to continue providing information to Health Canada on the safety, efficacy and quality of the vaccine to ensure the benefits of the vaccine continue to be demonstrated through market use.

The initial indication of the vaccine is for use in people 16 years of age or older. Pfizer-BioNTech are running further clinical trials on children of all age groups and the indication could be revised in the future to include children if the data from these studies support it.

The vaccine was authorized under Health Canada's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. This process allowed Health Canada to assess information submitted by the manufacturer as it became available during the product development process, while maintaining Canada's high standards.

Notice to the Media

Today, at 12:00pm (EST), Government of Canada officials will hold a news conference to provide an update on the approval of a COVID-19 vaccine.

Location

Sir John A Macdonald Building, Room 200
144 Wellington Street, Ottawa, Ontario

The media availability will also be held by teleconference.

Toll-free (Canada/US) dial-in number:

1-866-206-0153

Local dial-in number:

613-954-9003

Passcode: 1622050#

Contacts

Media Relations

Health Canada

613-957-2983

hc.media.sc@canada.ca

Search for related information by keyword: [Immunization](#) | [Health Canada](#) | [Canada](#) | [Coronavirus \(COVID-19\)](#) | [Immunization and vaccines](#) | [general public](#) | [statements](#)

Date modified:

2020-12-09